510（K）Summary of Safety and Effectiveness

JUN 2 1 2013

This summary of 510k safety and effectiveness is being submitted in according with 21CFR part 807.92

Submitter: Edan Instruments, Inc
3/F - B, Nanshan Medical
Equipments Park, Nanhai Rd 1019#,
shekou, Nanshan Shenzhen,
518067 P.R. China
Tel: +86755 26882220
Fax:+86 755 26882223

Contact person: Cherry Sun
Edan Instruments, Inc.

Preparing date: 2012-08-10

Proprietary Name: Central Monitoring System (model MFM-CMS)

Classification information: 870.1025 monitor, physiological, patient(with arrhythmia detection or alarms)
Class II

Product code: MHX

Predicate Devices: HYPERVISOR VI Central Monitoring System (K062194)

Device Description: The MFM-CMS Central Monitoring System is a software production which runs on PC platform with Microsoft Windows XP or Microsoft Windows 7 operating system. Through specified EDAN protocol, one MFM-CMS can connect with multi-monitor manufactured by EDAN to collect patients' information and monitoring data such as physiological waveforms, physiological parameters and alarms. The MFM-CMS can also send bidirectional control instructions to bedside monitors to change patients' information, alarm limits, and conduct NIBP measurements. The bedside Patient Physiological Monitors have been cleared by FDA under K101539, K120144, K110922, K113623, K113653 and K120173 separately. The monitoring information collect by the MFM-CMS can be saved and

printed. At the same time, the old records can be searched conveniently and quickly.

Device features:

- Connect maximum 64 bedside patient monitors with Ethernet.
- Waveforms of each bedside monitor that can be displayed on the MFM-CMS include:

2 ECG waveform
1 RESP waveform
1 PLETH waveform
8 IBP waveform
1 CO2 waveform
4 AG waveforms for CO2, O2, N2O and AA

- Parameters of each bedside monitor that can be displayed on the MFM-CMS include:

ECG: HR, ST value, PVCs
RESP: RR
NIBP: SYS, DIA, MAP
SPO2: SPO2, PR
IBP: ART, PA, CVP, RAP, ICP, LAP, P1, P2 (only IBP supported by the monitor will be displayed)
CO2: EtCO2, FiCO2, AwRR
TEMP: T1, T2, TD
AG: EtCO2, FiCO2, AwRR; EtO2, FiO2; EtN2O, FiN2O; HAL/ISO/ENF/SEV/DES: Et, Fi, MAC
C.O.: C.O., TB

- The central monitoring supports one or two displays. It can display up to 32 bedside monitors on one display and 64 bedside monitors on two displays simultaneously.
- 240-hour trend data, 72-hour waveform, 720 alarm events, 1~12 hour short trend, 720-group NIBP measurement review for each bedside monitor.
- Drug calculation and titration table.
- Print patient information, wave review, alarm review, trend review, NIBP review, and drug calculation result.
- Audible & visible alarm.

- Web observation in the hospital local area network.
- Bidirectional control
- HL7

Intended Use: MFM-CMS provides centralized monitoring and critical care management for patients monitored by EDAN bedside monitors. From MFM-CMS, clinicians can gain access to patient information for patients on the Network. MFM-CMS displays waveforms, parameters and alarm status of EDAN bedside monitors for up to 32 patients on a single screen or up to 64 patients using two screens.

Test Summary: The following quality assurance measures were applied to the development of the MFM-CMS.

- Software testing
- Risk analysis
- Safety testing
- Performance test

Conclusion: Verification and validation testing was done on MFM-CMS. This premarket notification submission demonstrates that the subject device MFM-CMS is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 21, 2013

Edan Instruments, Inc.
c/o Mr. Randy Jiang, Certification Engineer
3/F - B, Nanshan Medical Equipments Park
Nanhai Rd. 1019#
Shenzhen, Guangdong 518067
CHINA

Re: K120727
Trade/Device Names: MFM-CMS Central Monitoring System
Regulatory Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm (Including ST-segment Measurement and Alarm)
Regulatory Class: Class II (Two)
Product Code: MHX
Dated: June 3, 2013
Received: June 6, 2013

Dear Mr. Jiang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number:

Device Name: Central Monitoring System (model MFM-CMS)

MFM-CMS is a software application that is intended for use as a clinical data managing system (also referred to as a clinical information system - CIS).The MFM-CMS Central Monitoring System offers centralized physiological information management of adult, pediatric and neonatal patients which is automatically acquired from multiple bedside monitors. The MFM-CMS provides: collection, display and documentation of data from bedside monitors, viewing of patient physiologic data at remote locations and alarms when the results of the physiologic parameters exceed the user defined limit. It operates with off-the-shelf software and hardware. The system is intended for use in a hospital/clinical environment.

Prescription Use ___X___	Or	Over the Counter Use _____
(21 CFR Part 801 Subpart D)		(21 CFR Part 801 Subpart C)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Owen P. Faris -S
2013.06.21
15:01:01 -04'00'